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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,511	01/08/2007	Toshio Doi	3749-0124PUS1	8941

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

KEMMERER, ELIZABETH

ART UNIT	PAPER NUMBER
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1646

NOTIFICATION DATE	DELIVERY MODE
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11/17/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/571,511	Applicant(s) DOI ET AL.	
	Examiner Elizabeth C. Kemmerer, Ph.D.	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 15-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/10/06, 11/29/06, 1/3/08, 7/1/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group VI, claims 12-14, in the reply filed on 28 August 2008 is acknowledged. The traversal is on the ground(s) that claim 2 allegedly is not anticipated by Deininger et al. This is not found persuasive for the following reasons. Claim 2 recites a method of evaluating the degree of progress and/or the efficacy of treatment of proliferative diseases causing sclerosis, comprising measuring the expression of at least one substance selected from the group consisting of STAT3, phosphorylated STAT3, Smad1, phosphorylated Smad1, activin receptor-like kinase 1, activin receptor-like kinase 3 and bone morphogenetic proteins in a biological sample. The phrase "of evaluating the degree of progress and/or the efficacy of treatment of proliferative diseases causing sclerosis" is in the preamble, and thus is not accorded patentable weight. The method step, "measuring the expression of at least one substance selected from the group consisting of STAT3, phosphorylated STAT3, Smad1, phosphorylated Smad1, activin receptor-like kinase 1, activin receptor-like kinase 3 and bone morphogenetic proteins in a biological sample" is indeed taught by Deininger et al. as explained in the previous Office Action. Furthermore, a claim lacks a special technical feature if it fails to define subject matter that is free of the prior art. Therefore, prior art that renders claimed subject matter obvious also can be relied upon to demonstrate that a claim lacks a special technical feature.

Applicant's election with traverse of species 2), Smad1 or phosphorylated Smad1, in the reply filed on 28 August 2008 is acknowledged. The traversal is on the

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grounds that the examiner must extend the search to non-elected species once allowable subject matter based on the single elected species is identified. Applicant further argues that the search for all five proteins would not cause an undue burden. This is not found persuasive for the following reasons. First, examination of additional species is not properly conducted until a *generic* claim is determined to be allowable, not just the single elected species. Secondly, expansion of a required search by a factor of five is considered an undue search burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-11 and 15-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 28 August 2008.

Specification

The disclosure is objected to because of the following informalities: The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

Appropriate correction is required.

35 U.S.C. § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed to methods comprising a single step characterized as "judging." This is a mental process, which is not subject to patent protection. There is no other process step, such as contacting a cell or tissue with a test substance, or an assay step wherein expression of Smad1 is measured and compared to a control. Amending the claims to include such steps would obviate this rejection. However, support for new claim language should be identified in the specification, since new matter must be avoided.

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Monia et al. (US 6,013,522; issued 11 January 2000).

The claims recite methods of identifying substances effective in (A) preventing and/or treating proliferative diseases causing sclerosis (claim 12), (B) inhibiting the increase of extracellular matrix (claim 13), and (C) inhibiting the expression of $\alpha 1$ type IV collagen (claim 14). Each of these intentions is only recited in the preamble.

However, a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process, and where the body of the claim does not depend on

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the preamble for completeness but, instead, the process steps are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Each claim recites the identical method step. Patentable weight is given to the recited method step, i.e., comprising judging whether or not a test substance inhibits the expression of at least one substance selected from the group consisting of STAT3, phosphorylated STAT3, Smad1, and phosphorylated Smad1.

Monia et al. teach a method comprising judging whether or not a test substance, in this case an antisense compound, inhibits the expression of Smad1. See col. 34-35, Examples 9 and 10. Therefore, Monia et al. clearly anticipate the claimed methods.

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As discussed above, the preambles of claims 12-14 recite a specific purpose, goal, or intention, whereas the body of the claims does not depend on the preambles for completeness. Therefore, there is a disconnect between the preambles and the method steps. Thus, it would not be clear to the skilled artisan if the claims were directed to

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methods of identifying substances as per the preambles, or merely to methods of judging whether or not a test substance inhibits expression of STAT3 or Smad1.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ECK/

07 November 2008

/Elizabeth C. Kemmerer/
Elizabeth C. Kemmerer, Ph.D.
Primary Examiner, Art Unit 1646